UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,576	09/29/2004	Kazunori Kataoka	2004-1545A	2488

513 7590 10/20/2005

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
HAQ, SHAFIQUL	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/509,576	KATAOKA ET AL.	
	Examiner	Art Unit	
	Shafiqul Haq	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/30/05; 4/22/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

& 9/29/04

DETAILED ACTION

1. Applicants' Preliminary amendment filed December 29, 2004 and March 30, 2005 are acknowledged and entered.

2. Claims 1-15 are pending.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Although specific claims may be discussed in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

5. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 1 and 10 recites the terms "free electron metal fine particle", "metal oxide fine particle" and semiconductor fine particle". It is not clear what "metals" and "semiconductors" are encompassed in "free electron metal fine particle", "metal oxide fine particle" and semiconductor fine particle". The terms "metal" and "semiconductor" are generic terms that encompasses wide range of metals (e.g alkaline earth metal, earth metal, lanthanides, actinides etc) and semiconductors (e.g. Si, Ge, Sn, GaAs etc). Furthermore, the term "fine particle" in the claim is a relative term which also renders the claim indefinite. The terms "fine particle", "free electron metal fine particle", "metal oxide fine particle" and semiconductor fine

particle" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

7. The term "optionally protected functional groups" in claims 1 and 9 renders the claims indefinite because the term "optionally" is not a positive recitation and may be interpreted as the protected functional group not being a required component of the claimed invention.

8. Claim 1 recites the phrase "Y stands for .....**functional moiety X**, and functional moieties same as, or different from, X." Function of the "Y group or moiety" in the claim is not clear. When both the "X" and "Y" (i.e. when Y stands for functional moiety X) are the same functional moiety, do they (X and Y functional moieties) play the same function i.e. to bind biosensor chip surface?

   In claim 1, "L", "W1" and "W2" can be a linker. It is not clear what linkers are encompassed by the linkers "L", "W1" and "W2". Are the linkers encompassed by "L" different from or same as the linkers encompassed by "W1" and "W2"?

9. Claim1, lines 11-12 recite the phrase "functional moieties same as, or different from, X." The term "same as" is a relative term and mere perception of a person looking at them. This term is subjective and therefore, does not establish any metes and bounds to distinguish this term from another. It is unclear how much "similar" would be considered a "same as", rendering it unclear what materials would be encompassed by the term "same as". It is not clear the "functional moiety" is different from X in what respect? With respect to reactivity to biochips?

10. Claim 1 and claim 10, line 13 recites the phrase "linker or linkage portion". It is not clear what is encompassed by the term "linkage portion" as the term may encompass a "bond", any "functional group" or "any atom".

11. Claim 1 recites the phrase "X stands for a functional group or afunctional moiety capable of binding to biosensor chip surface". It is not clear whether the nanoparticle directly binds to biosensor chip surface through the "X" functional group or the nanoparticle is first bound to a binding partner/pair through "X" functional before being able to bind to biosensor chip surface.

12. Claim 1 and claim 10, lines 17-18 recite the term "may be same or different". The term "may be" is not a positive recitation which renders the claim indefinite. It is also unclear when W^2-PEG-W^1-L is "different" in (X- W^2-PEG-W^1-L)$_x$ and (X- W^1-PEG-W^2-L)$_y$, it is different in what respect? i.e. different in what groups or moieties (i.e. L, W1, W2, PEG) makes it different?

13. In claim 1, line 19 term "integers not less that 1" vague and indefinite because the term "not less than 1" is relative term, is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

14. The biosensor system of claims 1-3 and 10 do not require any specific binding partner/pair bound to biosensor chip or to nanoparticle. It is unclear how an analyte would be detected without the analyte first being bound to a specific binding partner and thus is it unclear how does this assay work?

15. With respect to claim 4, the linkage of "L" to "PCL" and "W1" are not clear. "L" in formula (I) is a bivalent linkage but the groups in claim 4 are disclosed as terminal groups (one open linkage) and therefore, it is unclear how (i.e. through which residue) these groups are linked to "PCL" and "W1".

16. Claims 12-15 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: determination steps to determine the change in the extent of linkage i.e. the steps how the "change in the extent of linkage" is determined.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over 1) Weiss et al (5,990,479) taken in combination with 2) Barry et al (US 2004/0126900 A1) and 3) Natan (US 6,025,202)

Claims of present invention relates to nanoparticle based biosensor system in which nanoparticle is linked to biomolecular target through a bifunctional PEG linker. Target biomolecules (binding partner/pair) are linked to nanoparticles (PCL) through the PEG bifunctional linker.

In the nanoparticle of formula (I) of present invention, when W^2-PEG-W^1-L is same in (X- W^2-PEG-W^1-L)$_x$ and (Y- W^2-PEG-W^1-L)$_y$, and when Y stands for functional moiety X, the polyethylene glycol (PEG) modified nanoparticle can be viewed as a nanoparticle linked with a PEG linker in which the other end of the linker has a functional moiety capable of binding to biomolecular targer (note that W^1 and W^2 can be a single bond and L stands for linker or linkage portion).

Weiss et al. in a method for producing semiconductor nanocrystal probes for biological applications disclose semiconductor nanoparticle linked to a affinity molecule through a linking agent. The linking agent comprises two linking portions (functional moieties). The first portion linked to the semiconductor nanocrystal and a second portion capable of linking to an affinity molecule (e.g. antibodies, nucleic acids, ligands, proteins etc) (see abstract, column 2, lines 34-36; column 5, lines 20-37 and column 6, lines 63-67). Weiss et al further disclose linking agent comprising amino, mercapto or silane functional groups (column 7, lines 25-46 and column 8, lines 7-46).

However, Weiss et al fail to disclose PEG linker to link nanoparticle to biomolecular target.

Barry et al in a method to produce water soluble nanoparticle, disclose nanoparticles linked to biomolecular target via a linker molecule (see abstract). The linker can be a bifunctional PEG linker terminated with same or different reactive functional moieties, with one end attached to nanoparticle and the other end functionalized with a affinity peptide or biomolecular target (paragraphs [0011] and

[0054-0056]). Barry et al also disclose that it is beneficial to functionalize the nanoparticle surface with PEG chain (lines 6-8 of paragraph [0054].

Natan et al. disclose biosensor chip (glass, metal etc.) containing binding partner on which nanoparticles are bonded through corresponding binding partner coupled to nanoparticle (see fig.1C; column 1, lines 1-10; column 7, lines 48-52) and detection of analyte from the measurement of change in electrical resistance or surface plasmon resonance (see abstract).

Therefore, given the fact that PEG linker is common and known in the art to link biomolecules (binding partner/pair) and PEG linker is beneficial to functionalize nanoparticle surface (Barry et al), it would have been obvious at the time of the invention to a person of ordinary skill in the art to use equivalent PEG linker in the method of Wess et al, with the expectation of producing PEG modified nanoparticle and use of biosensor chip would be obvious in the detection method which are common and known in the art with nanoparticle based detection (Natan).

19. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewart et al. (US 5922537) in view Katoaka et al (US 2003/0171506 A1) and Barry et al (US 2004/0126900 A1).

Claims of present invention relates to nanoparticle based biosensor system in which nanoparticle is linked to biomolecular target through a bifunctional PEG linker. Target biomolecules (binding partner/pair) are linked to nanoparticles (PCL) through the PEG bifunctional linker.

In the nanoparticle of formula (I) of present invention, when W^2-PEG-W^1-L is same in (X- W^2-PEG-W^1-L)$_x$ and (Y- W^2-PEG-W^1-L)$_y$, and when Y stands for functional moiety X, the polyethylene glycol (PEG) modified nanoparticle can be viewed as a nanoparticle linked with a PEG linker in which the other end of the linker has a functional moiety capable of binding to biomolecular targer (note that W^1 and W^2 can be a single bond and L stands for linker or linkage portion).

Ewart et al. disclose a biosensor system comprising metal nanoparticle (column 5, lines linked with second analyte (a binding partner) and biosensor chip reversibly bonded with first analyte (corresponding binding partner) (column 2, lines 45-67; column 4, lines 17-42). Different binding partners are disclosed for immobilizing to test surface (biochip) and nanoparticles (column 7, lines 39-67 and column 8, table 1) and the nanoparticles can be bonded to recognition molecule through a bifunctional linker (by introduction of functional group on nanoparticles such as semiconductors, metal oxides, metal and polymers) (column 6, lines 50-67), which are exemplified by linkers containing functional groups such as tricfunctional silanes (e.g. 3-aminopropyl triethoxysilane), monofunctional aminosilanes (4-aminobutyl dimethylmethoxysilane) or thiol-terminal silanes (column 6, lines 51-67 and column 7, lines 1-37. Ewart also discloses that the particles may have dielectric, paramagnetic and/or phosphorescent properties and are useful in a variety of competitive type assays (see abstract and column 9, lines 13-28). Competitive assay in which sample analyte displaces nanoparticle bound biomolecular target (i.e. second analyte or corresponding binding partner bound to nanoparticles) from test

surface are disclosed (column 2, lines 45-67; column 3, lines 1-5; column 4, lines 17-42; column 17, lines 1-17 and claims 1-13). Different detection methods based on different properties (e.g. capacitance, dielectric, magnetic and phosphorescence) are also disclosed (column 9, lines 13-28; column 17, lines 1-17; column 17, lines 18-52 and claims 5, 8, and 9).

Ewart et al., however, fail to disclose PEG linker to link nanoparticle to biomolecular target.

Katoaka et al disclose polymer composition containing polymer or copolymer having a mercapto group at one end and functional group or ligand at the other end and also having a polyethylene glycol segment for forming surface of a biosensor (e.g. metal surface of a sensor chip. See paragraph [0043]) utilizing surface plasmon resonance (see abstract and paragraph [0001]). The glycol modified polymer disclosed in this reference is the same as the polymer of formula (I) of claim 1 (paragraphs [0007-0023]). Katoaka et al disclose that polymer having ethylene glycol units reduce non-specific adsorption of proteins (paragraphs [0005] and [0007]).]). Katoaka et al also disclose coupling different ligands (e.g. antigen, antibody, nucleic acid, sugar, biotin etc) to the polymer linker (paragraph [0024]).

Katoaka et al however, fail to disclose using this glycol modified polymer in nanoparticle based detection system.

Barry et al in a method to produce water soluble nanoparticle, disclose nanoparticles linked to biomolecular target via a linker molecule (see abstract). The linker can be a bifunctional PEG linker terminated with same or different reactive

functional moieties, with one end attached to nanoparticle and the other end functionalized with a affinity peptide or biomolecular target (paragraphs [0011] and [0054-0056]). Barry et al also disclose that it is beneficial to functionalize the nanoparticle surface with PEG chain (lines 6-8 of paragraph [0054].

Therefore, given the fact that PEG linker is common and known in the art to link biomolecules (binding partner/pair) (Katoaka et al and Barry et al) and PEG linker is beneficial to functionalize nanoparticle surface (Barry et al), it would have been obvious at the time of the invention to a person of ordinary skill in the art to substitute linkers of Ewart's with equivalent PEG linker (Katoaka et al or Barry et al) in the biosensor system of Ewart et al., with the expectation of producing PEG modified nanoparticle based biosensor similarly useful for detection of analytes in a sample.

20. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewart et al. (US 5922537) in view Katoaka et al (US 2004/0038506 A1).

Claims of present invention relates to nanoparticle based biosensor system in which nanoparticle is linked to biomolecular target through a bifunctional PEG linker. Target biomolecules (binding partner/pair) are linked to nanoparticles (PCL) through the PEG bifunctional linker.

In the nanoparticle of formula (I) of present invention, when W^2-PEG-W^1-L is same in (X- W^2-PEG-W^1-L)$_x$ and (Y- W^2-PEG-W^1-L)$_y$, and when Y stands for functional moiety X, the polyethylene glycol (PEG) modified nanoparticle can be viewed as a nanoparticle linked with a PEG linker in which the other end of the linker

has a functional moiety capable of binding to biomolecular targer (note that W^1 and W^2 can be a single bond and L stands for linker or linkage portion).

Ewart et al. disclose a biosensor system comprising metal nanoparticle (column 5, lines linked with second analyte (a binding partner) and biosensor chip reversibly bonded with first analyte (corresponding binding partner) (column 2, lines 45-67; column 4, lines 17-42). Different binding partners are disclosed for immobilizing to test surface (biochip) and nanoparticles (column 7, lines 39-67 and column 8, table 1) and the nanoparticles can be bonded to recognition molecule through a bifunctional linker (by introduction of functional group on nanoparticles such as semiconductors, metal oxides, metal and polymers) (column 6, lines 50-67), which are exemplified by linkers containing functional groups such as tricfunctional silanes (e.g. 3-aminopropyl triethoxysilane), monofunctional aminosilanes (4-aminobutyl dimethylmethoxysilane) or thiol-terminal silanes (column 6, lines 51-67 and column 7, lines 1-37. Ewart also discloses that the particles may have dielectric, paramagnetic and/or phosphorescent properties and are useful in a variety of competitive type assays (see abstract and column 9, lines 13-28). Competitive assay in which sample analyte displaces nanoparticle bound biomolecular target (i.e. second analyte or corresponding binding partner bound to nanoparticles) from test surface are disclosed (column 2, lines 45-67; column 3, lines 1-5; column 4, lines 17-42; column 17, lines 1-17 and claims 1-13). Different detection methods based on different properties (e.g. capacitance, dielectric, magnetic and phosphorescence)

are also disclosed (column 9, lines 13-28; column 17, lines 1-17; column 17, lines 18-52 and claims 5, 8, and 9).

Ewart et al., however, fail to disclose PEG linker to link nanoparticle to biomolecular target.

Katoaka et al. disclose nanoparticle with a polymer having PEG unit and functional group to attach to nanoparticle and biomolecular targets (see abstract and paragraphs [0004], [0010], [0015], [0023], [0045]). The polymer disclose by Katoaka is the same as the polymer of claim 1 of present invention. Kataoka et al also disclose the dispersion stability is improved by using PEG modified polymer on metal particles (paragraph [0009]).

Therefore, given the fact that PEG linker is common and known in the art to link biomolecules (binding partner/pair) (Katoaka et al) and PEG linker is beneficial as it improves dispersion stability (Katoaka et al), it would have been obvious at the time of the invention to a person of ordinary skill in the art to substitute linkers of Ewart's with equivalent PEG linker (Katoaka et al) in the biosensor system of Ewart et al., with the expectation of producing PEG modified nanoparticle based biosensor similarly useful for detection of analytes in a sample.

Double Patenting

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/507,303 in view of Ewart et al and Barry et al (US 2004/0126900 A1).

Copending application 10/507,303 disclose polymer composition containing polymer or copolymer having a mercapto group or trialkoxysilyl at one end and functional group or ligand at the other end and also having a polyethylene glycol segment for forming surface of a biosensor (comprising semi-conductor, metal oxide etch). The glycol modified polymer disclosed in this reference is the same as the polymer of formula (I) of claim 1 (compare with claim 1 of copending application). Claims of the copending application disclose this polymer on biosensor surface but, fail to disclose this glycol modified polymer on nanoparticle and in nanoparticle based biosensor detection system.

Barry et al in a method to produce water soluble nanoparticle, disclose nanoparticles linked to biomolecular target via a linker molecule (see abstract). The linker can be a bifunctional PEG linker terminated with same or different reactive functional moieties, with one end attached to nanoparticle and the other end functionalized with a affinity peptide or biomolecular target (paragraphs [0011] and

[0054-0056]). Barry et al also disclose that it is beneficial to functionalize the nanoparticle surface with PEG chain (lines 6-8 of paragraph [0054].

Ewart et al. disclose a biosensor system comprising metal nanoparticle (column 5, lines linked with second analyte (a binding partner) and biosensor chip reversibly bonded with first analyte (corresponding binding partner) (column 2, lines 45-67; column 4, lines 17-42). Different binding partners are disclosed for immobilizing to test surface (biochip) and nanoparticles (column 7, lines 39-67 and column 8, table 1) and the nanoparticles can be bonded to recognition molecule through a bifunctional linker (by introduction of functional group on nanoparticles such as semiconductors, metal oxides, metal and polymers) (column 6, lines 50-67), which are exemplified by linkers containing functional groups such as tricfunctional silanes (e.g. 3-aminopropyl triethoxysilane), monofunctional aminosilanes (4-aminobutyl dimethylmethoxysilane) or thiol-terminal silanes (column 6, lines 51-67 and column 7, lines 1-37. Ewart also discloses that the particles may have dielectric, paramagnetic and/or phosphorescent properties and are useful in a variety of competitive type assays (see abstract and column 9, lines 13-28). Competitive assay in which sample analyte displaces nanoparticle bound biomolecular target (i.e. second analyte or corresponding binding partner bound to nanoparticles) from test surface are disclosed (column 2, lines 45-67; column 3, lines 1-5; column 4, lines 17-42; column 17, lines 1-17 and claims 1-13). Different detection methods based on different properties (e.g. capacitance, dielectric, magnetic and

phosphorescence) are also disclosed (column 9, lines 13-28; column 17, lines 1-17; column 17, lines 18-52 and claims

Therefore, given the fact that PEG linker is common and known in the art to use in biosensors (copending application) and PEG linker is beneficial to functionalize nanoparticle surface (Barry et al), it would have been obvious at the time of the invention to a person of ordinary skill in the art to substitute conventional linker with equivalent PEG linker (copending application) in the method of Ewart et al. to link biomolecule on nanoparticles, with the expectation of producing PEG modified nanoparticle based detection system useful for detection of biomolecular targets.

This is a provisional obviousness-type double patenting rejection.

23. Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/275,904 in view of Ewart et al and Barry et al (US 2004/0126900 A1).

Copending application 10/275,904 disclose polymer composition containing polymer or copolymer having a mercapto group one end and functional group or ligand at the other end and also having a polyethylene glycol segment for forming surface of a metal biosensor chip utilizing surface plasmon resonance (see claim 5). The glycol modified polymer disclosed in this reference is the same as the polymer of formula (I) of claim 1 (compare with claim 1 of copending application). Coupling of different ligands (e.g. antigen, antibody, nucleic acid, sugar, biotin etc) to the polymer linker is also disclosed (claim 3). Claims of the copending application

disclose this polymer on biosensor surface but fail to disclose this glycol modified polymer on nanoparticle and in nanoparticle based biosensor detection system.

Barry et al in a method to produce water soluble nanoparticle, disclose nanoparticles linked to biomolecular target via a linker molecule (see abstract). The linker can be a bifunctional PEG linker terminated with same or different reactive functional moieties, with one end attached to nanoparticle and the other end functionalized with a affinity peptide or biomolecular target (paragraphs [0011] and [0054-0056]). Barry et al also disclose that it is beneficial to functionalize the nanoparticle surface with PEG chain (lines 6-8 of paragraph [0054].

Ewart et al. disclose a biosensor system comprising metal nanoparticle (column 5, lines linked with second analyte (a binding partner) and biosensor chip reversibly bonded with first analyte (corresponding binding partner) (column 2, lines 45-67; column 4, lines 17-42). Different binding partners are disclosed for immobilizing to test surface (biochip) and nanoparticles (column 7, lines 39-67 and column 8, table 1) and the nanoparticles can be bonded to recognition molecule through a bifunctional linker (by introduction of functional group on nanoparticles such as semiconductors, metal oxides, metal and polymers) (column 6, lines 50-67), which are exemplified by linkers containing functional groups such as tricfunctional silanes (e.g. 3-aminopropyl triethoxysilane), monofunctional aminosilanes (4-aminobutyl dimethylmethoxysilane) or thiol-terminal silanes (column 6, lines 51-67 and column 7, lines 1-37. Ewart also discloses that the particles may have dielectric, paramagnetic and/or phosphorescent properties and are useful in a variety of

competitive type assays (see abstract and column 9, lines 13-28). Competitive assay in which sample analyte displaces nanoparticle bound biomolecular target (i.e. second analyte or corresponding binding partner bound to nanoparticles) from test surface are disclosed (column 2, lines 45-67; column 3, lines 1-5; column 4, lines 17-42; column 17, lines 1-17 and claims 1-13). Different detection methods based on different properties (e.g. capacitance, dielectric, magnetic and phosphorescence) are also disclosed (column 9, lines 13-28; column 17, lines 1-17; column 17, lines 18-52 and claims

Therefore, given the fact that nanoparticle based biosensor detection system is known and common in the art (Ewart et al) and PEG linker is beneficial to functionalize nanoparticle surface and biosensor surface (copending application and Barry et al), it would have been obvious at the time of the invention to a person of ordinary skill in the art to include nanoparticle coupled with PEG modified linker in the method of copending application, with the expectation of producing PEG modified nanoparticle based detection system useful for detection of biomolecular targets.

This is a provisional obviousness-type double patenting rejection.

Conclusion

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHAFIQUL HAQ
EXAMINER
ART UNIT 1641

MARY E. CEPERLEY
PRIMARY EXAMINER
ART UNIT 1641